

## **CERTIFICATE OF ANALYSIS**

Stat Profile® pHOx Ultra™ / CCX™ BUN Membrane Kit Lot Number 24337033 Part Number 48596 Exp Date 2026-03-02

Date of manufacture 2024-12-02

UDI# (01)00385480485968(11)241202(17)260302(10)24337033

	<u>Spec</u>	Mean Result
BUN Slope	9.30 - 12.90	12.42
CCX L 4	14 - 24	18
CCX L 5	49 - 63	55

This product is certified to have been manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector

Title

12/5/2024

Date